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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,706	07/22/2003	Ronald T. Sleeter	1533.6100001/PAJ/KPQ	4932

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EXAMINER

THERKORN, ERNEST G

ART UNIT

PAPER NUMBER

1723

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/623,706

Applicant(s)

SLEETER ET AL.

Examiner

Ernest G. Therkorn

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993. At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in reciting use of a silica column of at least 5 grams and a sample size of 150 mg to about 250 mg. Page 2, lines 7-12 of the specification asserts that Sebedio (JAOCS 63:1541-1543, 1986)'s columns are 690 mg. Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993, pages 14, 27, 42, 48, and Table 4 discloses that use of a 5 or 10 gram column allows a higher flow rate and a larger syringe size and that use of a cartridge with too small a capacity causes poor or variable recovery. Millipore Manual No. PN011188 Table 2 (Silica) discloses that silica is a desirable packing material for lipid classification. Millipore Manual No. PN011188, Table 4 indicates that a 500 mg-1 gram column has a syringe size of 6 cc and a 5 gram column has a syringe size of 20 cc, implying use of sample sizes  $3\frac{1}{3}$  larger in the 5 gram column. Sebedio (JAOCS 63:1541-1543, 1986) page 1542, column 2, lines 10 and 11 indicates good reproducibility was achieved when using a sample size of 50 mg. It would have been obvious to use a silica column of at least 5 grams because Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993, pages 14, 27, 42, 48, and Table 4 discloses that use of a 5 or 10 gram column allows a higher flow rate and a larger syringe size

and that use of a cartridge with too small a capacity causes poor or variable recovery and Millipore Manual No. PN011188 Table 2 (Silica) discloses that silica is a desirable packing material for lipid classification. It would have been obvious to use a sample size of 150 mg to about 250 mg because Millipore Manual No. PN011188, Table 4 indicates that a 500 mg-1 gram column has a syringe size of 6 cc and a 5 gram column has a syringe size of 20 cc, implying use of sample sizes  $3\frac{1}{3}$  larger in the 5 gram column and Sebedio (JAOCS 63:1541-1543, 1986) page 1542, column 2, lines 10 and 11 indicates good reproducibility was achieved when using a sample size of 50 mg.  $3\frac{1}{3}$  times 50 mg is within the range of 150 mg to about 250 mg.

Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 as applied to claims 1-22 above, and further in view of Hamilton (Lipids 23:1146-1149, 1988). At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 in reciting rinsing residue. Hamilton (Lipids 23:1146-1149, 1988) (page 1148, column 2, the second full paragraph) discloses that washing allows the cartridge to be reused. It would have been obvious to rinse in Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 because Hamilton (Lipids 23:1146-1149, 1988) (page 1148, column 2, the second full paragraph) discloses that washing allows the cartridge to be reused.

Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188,

pages 1-51 and 51-62, 1993 and Hamilton (Lipids 23:1146-1149, 1988) as applied to claims 9 and 19 above, and further in view of Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715. At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 and Hamilton (Lipids 23:1146-1149, 1988) and Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 in reciting heating. Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 discloses that heating reduces sample retention. It would have been obvious to heat in Sebedio (JAOCS 63:1541-1543, 1986) in view of Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 and Hamilton (Lipids 23:1146-1149, 1988) because Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 discloses that heating reduces sample retention.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Hamilton (Lipids 23:1146-1149, 1988) and Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993. At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in reciting use of a silica column of at least 5 grams and a sample size of 150 mg to about 250 mg. Page 2, lines 7-12 of the specification asserts that Sebedio (JAOCS 63:1541-1543, 1986)'s columns are 690 mg. Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993, pages 14, 27, 42, 48, and Table 4 discloses that use of a 5 or 10 gram column allows a higher flow rate and a larger syringe size and that use of a cartridge with too small a capacity causes poor or variable recovery. Millipore Manual No. PN011188 Table 2 (Silica) discloses that use of silica is a desirable packing material for lipid classification. Hamilton (Lipids 23:1146-

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1149, 1988) (page 1146, column 1, the second full paragraph) discloses that silica permits a 98% recovery of many lipids classes. Millipore Manual No. PN011188, Table 4 indicates that a 500 mg-1 gram column has a syringe size of 6 cc and a 5 gram column has a syringe size of 20 cc, implying use of sample sizes  $3\frac{1}{3}$  larger in the 5 gram column. Sebedio (JAOCS 63:1541-1543, 1986) page 1542, column 2, lines 10 and 11 indicates good reproducibility was achieved when using a sample size of 50 mg. It would have been obvious to use a silica column of at least 5 grams because Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993, pages 14, 27, 42, 48, and Table 4 discloses that use of a 5 or 10 gram column allows a higher flow rate and a larger syringe size and that use of a cartridge with too small a capacity causes poor or variable recovery, Millipore Manual No. PN011188 Table 2 (Silica) discloses that silica is a desirable packing material for lipid classification, and Hamilton (Lipids 23:1146-1149, 1988) (page 1146, column 1, the second full paragraph) discloses that use of silica permits a 98% recovery of many lipids classes. It would have been obvious to use a sample size of 150 mg to about 250 mg because Millipore Manual No. PN011188, Table 4 indicates that a 500 mg-1 gram column has a syringe size of 6 cc and a 5 gram column has a syringe size of 20 cc, implying use of sample sizes  $3\frac{1}{3}$  larger in the 5 gram column and Sebedio (JAOCS 63:1541-1543, 1986) page 1542, column 2, lines 10 and 11 indicates good reproducibility was achieved when using a sample size of 50 mg.  $3\frac{1}{3}$  times 50 mg is within the range of 150 mg to about 250 mg.

Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebedio (JAOCS 63:1541-1543, 1986) in view of Hamilton (Lipids 23:1146-1149,

1988) and Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 as applied to claims 9 and 19 above, and further in view of Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715. At best, the claims differ from Sebedio (JAOCS 63:1541-1543, 1986) in view of Hamilton (Lipids 23:1146-1149, 1988) and Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 in reciting heating. Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 discloses that heating reduces sample retention. It would have been obvious to heat in Sebedio (JAOCS 63:1541-1543, 1986) in Sebedio (JAOCS 63:1541-1543, 1986) in view of Hamilton (Lipids 23:1146-1149, 1988) and Millipore Manual No. PN011188, pages 1-51 and 51-62, 1993 because Snyder, Introduction to Modern Liquid Chromatography, 1979, page 715 discloses that heating reduces sample retention.

The remarks urge patentability based upon use of a sample size of 150 mg to about 250 mg. However, Millipore Manual No. PN011188, Table 4 indicates that a 500 mg-1 gram column has a syringe size of 6 cc and a 5 gram column has a syringe size of 20 cc, implying use of sample sizes  $3\frac{1}{3}$  larger in the 5 gram column. Sebedio (JAOCS 63:1541-1543, 1986) page 1542, column 2, lines 10 and 11 indicates good reproducibility was achieved when using a sample size of 50 mg. It would have been obvious to use a sample size of 150 mg to about 250 mg because Millipore Manual No. PN011188, Table 4 indicates that a 500 mg-1 gram column has a syringe size of 6 cc and a 5 gram column has a syringe size of 20 cc, implying use of sample sizes  $3\frac{1}{3}$  larger in the 5 gram column and Sebedio (JAOCS 63:1541-1543, 1986) page 1542,

column 2, lines 10 and 11 indicates good reproducibility was achieved when using a sample size of 50 mg.  $3\frac{1}{3}$  times 50 mg is within the range of 150 mg to about 250 mg.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is (703) 872-9306.

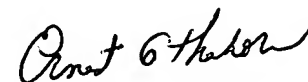
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Business Center (EBC) at 866-217-9197 (toll-free).



**Ernest G. Therkorn**  
**Primary Examiner**  
**Art Unit 1723**

EGT  
April 4, 2005